Eric I. Abraham Christina L. Saveriano

HILL WALLACK LLP

21 Roszel Road

Princeton, New Jersey 08540 Telephone: 609-924-0808 Facsimile: 609-452-1888 <u>eabraham@hillwallack.com</u> csaveriano@hillwallack.com

Attorneys for Defendant Richard P. Junghans, M.D., Ph.D.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IMMUNOMEDICS, INC.,)	
Plaintiff,)	Civil Action No. 15-cv-04526 JLL-
Fiantini,)	JAD
v.)	
)	Judge Jose L. Linares
ROGER WILLIAMS MEDICAL CENTER,)	
RICHARD P. JUNGHANS, M.D., Ph.D.,)	JURY TRIAL DEMANDED
STEVEN C. KATZ, M.D., TUFTS)	
MEDICAL CENTER, BDL PRODUCTS,)	
INC., CARGENIX HOLDINGS, LLC, TNK-)	
THERAPEUTICS, INC., SORRENTO)	
THERAPEUTICS, INC.,)	
)	
Defendants.)	
)	

DR. RICHARD P. JUNGHANS' ANSWER TO THIRD AMENDED COMPLAINT

Defendant Dr. Richard P. Junghans ("Junghans" or "Defendant") hereby responds to the numbered paragraphs of the Third Amended Complaint ("TAC") of Immunomedics, Inc. ("Immunomedics" or "Plaintiff") as follows:

NATURE OF THE CASE

- 1. Junghans denies the allegations of Paragraph 1.
- 2. Junghans admits that pursuant to several Material Transfer Agreements, the contents of which speak for themselves, he received from Immunomedics and used Research

Material as defined in and permitted by those agreements, and otherwise denies the allegations of Paragraph 2.

- 3. Junghans denies the allegations of Paragraph 3.
- 4. Junghans denies the allegations of Paragraph 4.
- 5. Junghans denies the allegations of Paragraph 5.
- 6. Junghans denies the allegations of Paragraph 6.
- 7. Junghans denies the allegations of Paragraph 7.
- 8. Paragraph 8 of the TAC is not directed at Junghans, thus no response is necessary. To the extent that a response is necessary, Junghans denies the allegations of Paragraph 8.
- 9. Junghans responds to paragraph 9 of the TAC by stating that the referenced agreement speaks for itself.
- 10. Admitted, although Junghans denies the implications that he had any obligation to seek the issuance of a waiver or declination of licensing and other rights by Immunomedics.
- 11. Junghans admits that TNK agreed to indemnify him in connection with claims brought by Immunomedics. Junghans denies the remaining allegations of Paragraph 11.
 - 12. Junghans denies the allegations of Paragraph 12.
 - 13. Admitted.
- 14. Junghans lacks the information necessary to admit or deny the allegations of the first sentence of Paragraph 14. Junghans denies the allegations of the second sentence of Paragraph 14.
 - 15. Junghans states that the referenced agreement speaks for itself.
- Junghans admits that on or about July 16, 2015 BDL Products, Inc. was created.Junghans denies the remaining allegations of Paragraph 16.
 - 17. Denied.

- 18. Junghans lacks the information necessary to admit or deny the allegations of Paragraph 18.
 - 19. Junghans denies the allegations of Paragraph 19.

PARTIES

- 20. Junghans admits that Immunomedics is a biopharmaceutical company. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 20, and therefore denies the remaining allegations.
- 21. Junghans admits that RWMC is an academic medical center that conducts cancer research and treats cancer patients. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 21, and therefore denies the remaining allegations.
 - 22. Junghans admits the allegations of Paragraph 22.
 - 23. Junghans admits the allegations of Paragraph 23.
- 24. Junghans admits the allegations of the first sentence of Paragraph 24. Junghans denies the remaining allegations of Paragraph 24.
- 25. Junghans admits the allegations of the first sentence of Paragraph 25. Junghans denies the remaining allegations of Paragraph 25.
- 26. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 26, and therefore denies those allegations.
- 27. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 27, and therefore denies those allegations.

JURISDICTION AND VENUE

28. Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans admits that Plaintiff's Third Amended Complaint

alleges patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271, and alleges diversity jurisdiction. Junghans admits that a Material Transfer Agreement signed on December 11, 2008 ("2008 MTA") contains a "Governing Law provision," the contents of which speak for themselves in the context of that document. Junghans admits that he has visited Immunomedics and that Dr. Katz has visited Immunomedics. Junghans otherwise denies the allegations of Paragraph 28.

FACTUAL BACKGROUND

- 29. Paragraph 293 contains an improper narrative to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 29, and therefore denies the allegations.
- 30. Paragraph 30 contains an improper narrative to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 30, and therefore denies the allegations.
- 31. Junghans admits that Immunomedics entered into: (a) a Material Transfer

 Agreement signed on September 16, 1993 and September 17, 1993 ("1993 MTA"); (b) the 2008

 MTA; and (c) a Material Transfer Agreement signed on May 6, 2010 and May 13, 2010 ("2010 MTA"), the contents of each of which speak for themselves in the context of those documents, and otherwise denies the allegations of Paragraph 31.

THE 1993 MTA

32. Junghans admits that there is a Material Transfer Agreement signed on September 16, 1993, and September 17, 1993, the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 32.

- 33. Junghans admits that there is a 1993 MTA, the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 33.
- 34. The allegations of Paragraph 34 purport to paraphrase portions of the 1993 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 34.
- 35. The allegations of Paragraph 35 purport to paraphrase portions of the 1993 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 35.
- 36. The allegations of Paragraph 36 purport to quote portions of the 1993 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 36.
- 37. The allegations of Paragraph 37 purport to quote portions of the 1993 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 37.
- 38. The allegations of Paragraph 38 purport to quote portions of the 1993 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 38.
- 39. The allegations of Paragraph 39 purport to paraphrase and quote portions of the 1993 MTA, the contents of which speak for themselves in the context of that document.

 Junghans otherwise denies the allegations of Paragraph 39.
 - 40. Junghans denies the allegations of Paragraph 40.
 - 41. Junghans denies the allegations of Paragraph 41.

42. Junghans admits that the 1993 MTA contains a provision entitled "Governing Law," the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 42.

THE 2008 MTA

- 43. Junghans admits the allegations of Paragraph 43.
- 44. Junghans admits that there is a Material Transfer Agreement dated December 11, 2008 ("2008 MTA"), the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 44.
- 45. The allegations of Paragraph 45 purport to describe provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 45.
- 46. The allegations of Paragraph 46 purport to describe provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 46.
- 47. The allegations of Paragraph 47 purport to quote provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 47.
- 48. The allegations of Paragraph 48 purport to quote provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 48.
- 49. The allegations of Paragraph 49 purport to quote provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 49.

- 50. The allegations of Paragraph 50 purport to quote provisions of the 2008 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 50.
 - 51. Junghans denies the allegations of Paragraph 51.
- 52. Junghans admits that the 1993 MTA contains a provision entitled "Governing Law," the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 52.

THE 2010 MTA

- 53. Junghans admits that there is a Material Transfer Agreement signed on May 6, 2010, and May 13, 2010, the contents of which speak for themselves in the context of that document, and otherwise denies the allegations of Paragraph 53.
- 54. The allegations of Paragraph 54 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 54.
- 55. The allegations of Paragraph 55 purport to describe provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 55.
- 56. The allegations of Paragraph 56 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 56.
- 57. The allegations of Paragraph 57 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 57.

- 58. The allegations of Paragraph 58 purport to describe provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 58.
- 59. The allegations of Paragraph 59 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 59.
- 60. The allegations of Paragraph 60 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 60.
- 61. The allegations of Paragraph 61 purport to describe provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 61.
- 62. The allegations of Paragraph 62 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 62.
- 63. The allegations of Paragraph 63 purport to quote provisions of the 2010 MTA, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 63.
 - 64. Junghans denies the allegations of Paragraph 64.
- 65. The allegations of Paragraph 65 purport to quote and describe provisions of an August 5, 2015 letter, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 65.
 - 66. Junghans denies the allegations of Paragraph 66.

DEFENDANTS' ALLEGEDLY WRONGFUL CONDUCT REGARDING THE MTAS

- 67. Junghans admits that U.S. Patent 5,874,540 ("the '540 patent"), entitled "CDR-Grafted Type III Anti-CEA Humanized Mouse Monoclonal Antibodies," bears an issue date of February 23, 1999, and lists on its face Immunomedics, Inc. as assignee. Junghans admits that U.S. Patent No. 6,676,924 ("the '924 patent"), entitled "CDR-grafted type III anti-CEA humanized mouse monoclonal antibodies," bears an issue date of January 13, 2004, and lists Immunomedics, Inc. as assignee. Junghans admits that U.S. Patent No. 6,926,893 ("the '893 patent"), entitled "Multi-stage cascade boosting vaccine," bears an issue date of August 9, 2005, and lists Immunomedics, Inc. as assignee. Junghans otherwise denies the allegations of Paragraph 67.
 - 68. Junghans denies the allegations of Paragraph 68.
- 69. Junghans admits that U.S. Patent Application Publication No. 2002-0165360, entitled "Chimeric Effector Cell Receptors Against Carcinoembryonic Antigen," published on November 7, 2002, listing on its face Richard P. Junghans as assignee, and otherwise denies the allegations of Paragraph 69.
- 70. The allegations of Paragraph 70 purport to quote portions of the '360 publication, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 70.
- 71. Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 71, and therefore denies the allegations.
 - 72. Junghans denies the allegations of Paragraph 72.

- 73. Junghans admits that Dr. Katz is affiliated with RWMC and that Dr. Katz assisted Junghans in conducting studies, and otherwise denies the allegations of Paragraph 73.
- 74. Junghans admits that he has collaborated with Dr. Katz on research projects. Junghans denies the remaining allegations of Paragraph 74.
- 75. Junghans admits that he is a named co-author on the manuscript "Neutrophil: lymphocyte ratios and serum cytokine changes...", published in *Cancer Gene Therapy* in November 2014, which lists his institutional affiliation, and otherwise denies the allegations of Paragraph 75.
- 76. The allegations of Paragraph 76 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 76.
- 77. Junghans admits that he is a named co-author on the manuscript "Liver myeloid-derived suppressor cells expand...", published in *Cancer Immunology, Immunotherapy* in July 2015, which lists his institutional affiliation, and otherwise denies the allegations of Paragraph 77.
- 78. The allegations of Paragraph 78 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 78.
- 79. Junghans admits that he is a named co-author on the manuscript "2nd Generation Anti-CEA Designer T Cells Resist Activation-Induced Cell Death, Proliferate on Tumor Contact, Secrete Cytokines and Exhibit Superior Anti-Tumor Activity In Vivo: A Preclinical Evaluation," published in *Clinical Cancer Research* (December 15, 2008), which lists his institutional affiliation, and otherwise denies the allegations of Paragraph 79.

- 80. Junghans admits that he is a named author on the report "T-Cell Gene Therapy to Eradicate Disseminated Breast Cancers," prepared for U.S. Army Medical Research and Material Command, Fort Detrick, Maryland and dated May 2011, and that RWMC is identified as the contracting organization, and otherwise denies the allegations of Paragraph 80.
- 81. The allegations of Paragraph 81 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 81.
- 82. Junghans admits that he is a named co-author on the manuscript "Anti-HIV Designer T Cells Progressively Eradicate a Latently Infected Cell Line by Sequentially Inducing HIV Reactivation then Killing the Newly Gp120-Positive Cells," published in *Virology* (November 2013), which lists his institutional affiliation, and otherwise denies the allegations of Paragraph 82.
- 83. The allegations of Paragraph 83 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 83.
- 84. The allegations of Paragraph 84 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 84.
 - 85. Junghans denies the allegations of Paragraph 85.
- 86. The allegations of Paragraph 86 purport to describe portions of the MTAs, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 86.

- 87. Junghans admits that he left stocks of WI2 in the possession of Dr. Katz and RWMC when Junghans left RWMC. Junghans denies the remaining allegations of Paragraph 87.
 - 88. Junghans denies the allegations of Paragraph 88.
- 89. Junghans admits that he received a letter from Plaintiff dated May 8, 2015 ("May 8, 2015 Letter"), the contents of which speak for themselves, and otherwise denies the allegations of Paragraph 89.
- 90. Junghans admits that he received the May 8, 2015 Letter from Plaintiff, the contents of which speak for themselves, and otherwise denies the allegations of Paragraph 90.
- 91. Junghans admits that the May 8, 2015 Letter included the addresses for RWMC and TMC, and otherwise denies the allegations of Paragraph 91.
 - 92. Junghans denies the allegations of Paragraph 92.
- 93. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 93 and therefore denies the allegations.
- 94. The allegations of Paragraph 94 are not directed at Junghans; therefore no response is required. To the extent that a response is required, Junghans denies Paragraph 94.
- 95. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 95 and therefore denies the allegations.
- 96. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 96 and therefore denies the allegations.
 - 97. Junghans denies the allegations of Paragraph 97.
- 98. Junghans admits that he received a letter from Plaintiff dated May 27, 2015, the contents of which speak for themselves, and otherwise denies the allegations of Paragraph 98.
 - 99. Junghans denies the allegations of Paragraph 99.

- 100. Junghans admits that he sent a letter to Immunomedics dated August 5, 2015, the contents of which speak for themselves, and otherwise denies the allegations of Paragraph 100.
 - 101. Junghans denies the allegations of Paragraph 101.
 - 102. Junghans denies the allegations of Paragraph 102.

DEFENDANTS' ALLEGEDLY WRONGFUL CONDUCT REGARDING THE COMMERCIAL EXPLOITATION OF IMMUNOMEDICS' RESEARCH MATERIAL

- 103. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 103 and therefore denies the allegations.
 - 104. Junghans denies the allegations of Paragraph 104.
 - 105. Junghans admits the allegations of Paragraph 105.
 - 106. Junghans denies the allegations of Paragraph 106.
- 107. Junghans admits the allegations of the first sentence of Paragraph 107, but denies the remaining allegations of Paragraph 107.
- 108. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 108, and therefore denies the allegations.
 - 109. Junghans denies the allegations of Paragraph 109.
- 110. Junghans admits the allegations of the first two sentences of Paragraph 110, but denies the remaining allegations of Paragraph 110.
 - 111. Junghans denies the allegations of Paragraph 111.
- 112. The allegations of Paragraph 112 purport to describe and quote portions of the various agreements, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 112.
- 113. Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 113, and therefore denies the allegations.

- 114. The allegations of Paragraph 114 purport to describe and quote portions of the referenced agreement, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 114.
- 115. The allegations of Paragraph 115 purport to describe and quote portions of the referenced press release, the contents of which speak for themselves in the context of those documents. Junghans otherwise denies the allegations of Paragraph 115.
- 116. The allegations of Paragraph 116 purport to describe and quote portions of the referenced agreement, the contents of which speak for themselves in the context of that document. Junghans otherwise denies the allegations of Paragraph 116.
 - 117. Junghans denies the allegations of paragraph 117.
 - 118. Junghans denies the allegations of paragraph 118.
 - 119. Junghans denies the allegations of paragraph 119.
 - 120. Junghans denies the allegations of paragraph 120.
 - 121. Junghans denies the allegations of paragraph 121.
 - 122. Junghans denies the allegations of paragraph 122.
- 123. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 123 and therefore denies the allegations.
- 124. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 124 and therefore denies the allegations.
- 125. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 125 and therefore denies the allegations.

ANSWER TO FIRST COUNT

(Alleged Breach of Contract: Failure to Return Research Materials – RWMC and Dr. Junghans)

- 126. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-125.
 - 127. Junghans denies the allegations of Paragraph 127.
 - 128. Junghans denies the allegations of Paragraph 128.
 - 129. Junghans denies the allegations of Paragraph 129.
- 130. No response is required to Plaintiff's request for judgment against RWMC and Junghans in Paragraph 130. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO SECOND COUNT

(Alleged Breach of Contract: Improper Use and Sharing of the Research Materials – RWMC and Dr. Junghans)

- 131. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-130.
 - 132. Junghans denies the allegations of Paragraph 132.
 - 133. Junghans denies the allegations of Paragraph 133.
 - 134. Junghans denies the allegations of Paragraph 134.
 - 135. Junghans denies the allegations of Paragraph 135.

136. No response is required to Plaintiff's request for judgment against RWMC and Junghans in Paragraph 136. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO THIRD COUNT

(Breach of Contract: Failure to Provide Immunomedics with the Right of First Refusal – RWMC and Dr. Junghans)

- 137. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-136.
 - 138. Junghans denies the allegations of Paragraph 138.
 - 139. Junghans denies the allegations of Paragraph 139.
 - 140. Junghans denies the allegations of Paragraph 140.
 - 141. Junghans denies the allegations of Paragraph 141.
- 142. No response is required to Plaintiff's request for judgment against RWMC and Junghans in Paragraph 142. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO FOURTH COUNT (Alleged Conversion – All Defendants)

143. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required,

Junghans realleges and incorporates his answer to each allegation set forth above in response to Paragraphs 1-142.

- 144. Junghans admits that the 1993 MTA, the 2008 MTA, and the 2010 MTA each contain provisions regarding Research Material and Research Product, the contents of each of which speak for themselves in the context of those documents. Otherwise, denied.
 - 145. Junghans denies the allegations of Paragraph 145.
 - 146. Junghans denies the allegations of Paragraph 146.
 - 147. Junghans denies the allegations of Paragraph 147.
 - 148. Junghans denies the allegations of Paragraph 148.
 - 149. Junghans denies the allegations of Paragraph 149.
 - 150. Junghans denies the allegations of Paragraph 150.
 - 151. Junghans denies the allegations of Paragraph 151.
 - 152. Junghans denies the allegations of Paragraph 152.
 - 153. Junghans denies the allegations of Paragraph 153.
 - 154. Junghans denies the allegations of Paragraph 154.
 - 155. Junghans denies the allegations of Paragraph 155.
- 156. No response is required to Plaintiff's request for judgment in Paragraph 156. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO FIFTH COUNT

(Alleged Tortious Interference – Dr. Katz, BDL Products, Cargenix, TNK, and Sorrento)

157. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates his answer to each allegation set forth above in response to Paragraphs 1-156.

- 158. Junghans admits that the 1993 MTA, the 2008 MTA, and the 2010 MTA each contain provisions regarding Research Material and Research Product, the contents of each of which speak for themselves in the context of those documents. Otherwise, denied.
- 159. Junghans lacks knowledge and/or information sufficient to form a belief as to the truth of the allegations asserted in Paragraph 159 and therefore denies the allegations.
 - 160. Junghans denies the allegations of Paragraph 160.
 - 161. Junghans denies the allegations of Paragraph 161.
 - 162. Junghans denies the allegations of Paragraph 162.
 - 163. Junghans denies the allegations of Paragraph 163.
 - 164. Junghans denies the allegations of Paragraph 164.
 - 165. Junghans denies the allegations of Paragraph 165.
- 166. No response is required to Plaintiff's request for judgment in Paragraph 166. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO SIXTH COUNT (Alleged Unjust Enrichment – All Defendants)

- 167. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-166.
 - 168. Junghans denies the allegations of Paragraph 168.
 - 169. Junghans denies the allegations of Paragraph 169.
 - 170. Junghans denies the allegations of Paragraph 170.
 - 171. Junghans denies the allegations of Paragraph 171.

172. No response is required to Plaintiff's request for judgment in Paragraph 172. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any judgment.

ANSWER TO SEVENTH COUNT (Alleged Patent Infringement: '540 Patent – Defendants RWMC,

Dr. Junghans, and Dr. Katz)

- 173. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-172.
- 174. Junghans admits that the '540 patent is entitled "CDR-grafted type III anti-CEA humanized mouse monoclonal antibodies."
- 175. Junghans admits that the '540 patent bears an issue date of February 23, 1999, and otherwise denies the allegations of Paragraph 175.
- 176. Paragraph 176 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 176, and therefore denies the allegations.
- 177. Junghans does not contest the expiration date of the '540 patent as February 23, 2016.
- 178. Junghans admits that the '540 patent lists Immunomedics, Inc. as assignee, and otherwise denies the allegations of Paragraph 178.
- 179. Paragraph 179 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to

form a belief about the truth of the allegations in Paragraph 179, and therefore denies the allegations.

- 180. Junghans denies the allegations of Paragraph 180.
- 181. Junghans denies the allegations of Paragraph 181.
- 182. Junghans denies the allegations of Paragraph 182.
- 183. Junghans denies the allegations of Paragraph 183.
- 184. Junghans denies the allegations of Paragraph 184.
- 185. Junghans denies the allegations of Paragraph 185.
- 186. Junghans denies the allegations of Paragraph 186.

ANSWER TO EIGHTH COUNT

(Alleged Patent Infringement: '924 Patent – Defendants RWMC, Dr. Junghans, and Dr. Katz)

- 187. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-186.
- 188. Junghans admits that the '924 patent is entitled "CDR-grafted type III anti-CEA humanized mouse monoclonal antibodies."
- 189. Junghans admits that the '924 patent bears an issue date of January 13, 2004, and otherwise denies the allegations of Paragraph 189.
- 190. Paragraph 190 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 190, and therefore denies the allegations.
 - 191. Junghans does not contest that the '924 patent has expired.

- 192. Junghans admits that the '924 patent lists Immunomedics, Inc. as assignee, and otherwise denies the allegations of Paragraph 192.
- 193. Paragraph 193 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 193, and therefore denies the allegations.
 - 194. Junghans denies the allegations of Paragraph 194.
 - 195. Junghans denies the allegations of Paragraph 195.
 - 196. Junghans denies the allegations of Paragraph 196.
 - 197. Junghans denies the allegations of Paragraph 197.
 - 198. Junghans denies the allegations of Paragraph 198.
 - 199. Junghans denies the allegations of Paragraph 199.

ANSWER TO NINTH COUNT

(Alleged Patent Infringement – '893 Patent – Defendants RWMC, Dr. Junghans, and Dr. Katz)

- 200. No response is required to Plaintiff's incorporation by reference of the foregoing Paragraphs of its Third Amended Complaint. To the extent a response is deemed required, Junghans realleges and incorporates herein his answer to each allegation set forth above in response to Paragraphs 1-199.
- 201. Junghans admits that the '893 patent is entitled "Multi-stage cascade boosting vaccine."
- 202. Junghans admits that the '893 patent bears an issue date of August 9, 2005, and otherwise denies the allegations of Paragraph 202.
- 203. Paragraph 203 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to

form a belief about the truth of the allegations in Paragraph 203, and therefore denies the allegations.

- 204. Junghans does not contest that the '893 patent has expired.
- 205. Junghans admits that the '893 patent lists Immunomedics, Inc. as assignee, and otherwise denies the allegations of Paragraph 205.
- 206. Paragraph 206 states a legal conclusion to which no response is required. To the extent a response is deemed required, Junghans lacks knowledge and/or information sufficient to form a belief about the truth of the allegations in Paragraph 206, and therefore denies the allegations.
 - 207. Junghans denies the allegations of Paragraph 207.
 - 208. Junghans denies the allegations of Paragraph 208.
 - 209. Junghans denies the allegations of Paragraph 209.
 - 210. Junghans denies the allegations of Paragraph 210.
 - 211. Junghans denies the allegations of Paragraph 211.
 - 212. Junghans denies the allegations of Paragraph 212.

PRAYER FOR RELIEF

A response is not required to Plaintiff's prayer for relief. To the extent a response is deemed required, Junghans denies that Plaintiff is entitled to any relief whatsoever, either as prayed for or otherwise.

JUNGHANS' AFFIRMATIVE DEFENSES

1. Junghans asserts the following affirmative defenses without prejudice to the denials in this Answer and without admitting any allegations of the Third Amended Complaint not otherwise admitted. The affirmative defenses to the claims alleged in the Third Amended Complaint are based on knowledge or information known or available at this time or believed by

Junghans to be true at this time. Junghans does not admit or acknowledge that he bears the burden of proof as to these affirmative defenses. Junghans reserves the right to add any additional defenses based on his ongoing investigation and discovery.

First Affirmative Defense (Non- Infringement)

- 2. Junghans did not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '540 patent, the '924 patent, or the '893 patent before those patents expired.
- 3. Junghans did not induce or contribute to the infringement of any valid and enforceable claim of the '540 patent, the '924 patent, or the '893 patent before those patents expired.
- 4. The accused Research Products the scFv, CAR and CAR-T constructs allegedly containing the MN-14 variable region sequences created by Junghans did not infringe, either literally, or under the doctrine of equivalents, any claim of the '540 patent or '924 patent before those patents expired. The '540 and '924 patents are directed to humanized MN-14 antibody, methods for expressing the humanized MN-14 antibody, and methods of diagnosis and treatment using a conjugate that contains humanized MN-14 antibody. The scFv, CAR and CAR-T constructs created by Junghans are not antibodies or antibody conjugates.

Second Affirmative Defense (Safe Harbor)

5. The safe harbor exemption to infringement codified at 35 U.S.C. §271(e)(1) encompasses Junghans' research employing Research Material or Research Product. All of Junghans' uses of anti-CEA CAR constructs, anti-CEA CAR T cells, and any antibody, both prior to and after the expiration of the patents-in-suit, were reasonably related to the development and submission of information to the FDA under Federal law that regulates the manufacture, use,

or sale of drugs. Junghans' uses are therefore not acts of infringement under 35 U.S.C. \$271(e)(1).

- 6. Section 271(e)(1) "exempt[s] from infringement all uses of patented compounds 'reasonably related to the process of developing information for submission under any federal law regulating the manufacture, use or distribution of drugs." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372, 2383 (2005). The "use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA." *Id.* at 2383-84; *see also Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1341 (Fed. Cir. 2007) (finding on remand that "under the Supreme Court's statutory interpretation, the FDA Exemption applies to experiments conducted to determine the optimum candidate drug, including experiments with rejected candidates" and experiments that develop "information about the rationale for the drug, its structure, its toxicology, its mode of action, its effectiveness under different conditions, its side effects, its formulation, its administration, and like information.")
- 7. All of Junghans' research employing Research Material or Research Product was relevant to an Independent New Drug Application ("IND"), FDA BB IND 10791 held by Junghans for anti-CEA designer T cell constructs. All clinical research conducted by Junghans employing Research Material or Research Product was conducted pursuant to FDA BB IND 10791.
- 8. The preclinical research conducted by Junghans employing Research Product falls within the safe harbor exemption because the experiments produced information relevant to FDA BB IND 10791.

Third Affirmative Defense (Invalidity)

9. The '540 patent, the '924 patent, and the '893 patent, and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

Fourth Affirmative Defense (Patent Misuse)

10. Plaintiff has attempted to extend the physical and/or temporal scope of the '540 patent, the '924 patent, and the '893 patent beyond their legally permissible scope with intended anticompetitive effects. Accordingly, the claims of the '540 patent, the '924 patent, and the '893 patent are unenforceable for patent misuse.

Fifth Affirmative Defense (Laches/Estoppel)

11. Plaintiff's breach of contract claims, unjust enrichment claims, and claims of infringement of the '540 patent, the '924 patent, and the '893 patent are barred by laches and/or estoppel. Plaintiff has been aware that Junghans created anti-CEA CAR constructs incorporating hMN-14 sequence since at least as early as 1999 when the manuscript Nolan et al., Bypassing Immunization: Optimized Design of "Designer T Cells" against Carcinoembryonic Antigen (CEA)-expressing Tumors, and Lack of Suppression by Soluble CEA, *Clinical Cancer Research* Vol. 5, 3928-3941 was published. Despite this, Plaintiff waited until 2015 to bring this lawsuit over such constructs.

<u>Sixth Affirmative Defense</u> (Statute of Limitations)

12. Plaintiff's claims for breach of contract are barred by the statute of limitations.

Seventh Affirmative Defense (Failure to Mitigate)

13. Plaintiff has failed to exercise reasonable efforts to mitigate its alleged damages.

Eighth Affirmative Defense (Unclean Hands)

14. Junghans has been injured by Immunomedics' fraud, unconscionable conduct and bad faith.

Ninth Affirmative Defense (No Injury-in-Fact or Damages)

15. Plaintiff's claims are barred, in whole or in part, because it has not suffered any injury-in-fact or damages.

Tenth Affirmative Defense (No Causation)

16. Plaintiff's claims are barred to the extent that Plaintiff's claims, alleged injuries and alleged damages were not caused by any act or omission of Junghans.

Eleventh Affirmative Defense (Failure to State a Claim)

17. Plaintiff has failed to state a claim on which relief can be granted.

Twelfth Affirmative Defense (No Exceptional Case)

18. Junghans' actions do not give rise to an exceptional case justifying awarding Plaintiff any attorneys' fees under 35 U.S.C. § 285.

WHEREFORE, Junghans respectfully requests that the Court grant him the following relief:

- A. Entry of judgment in favor of Junghans on Plaintiff's Third Amended Complaint;
- B. Dismissal of each count of Plaintiff's Third Amended Complaint with prejudice;

- C. An Order denying all relief sought by Plaintiff;
- D. The entry of an order declaring that this case is exceptional, and awarding Junghans his costs, expenses and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules and common law;
 - E. An award of costs and reasonable attorneys' fees to Junghans; and
 - F. An Order granting other such relief as the Court deems just and proper.

DEMAND FOR A JURY TRIAL

Junghans demands a trial by jury for all issues so triable pursuant to Federal Rule of Civil Procedure 38(b).

Dated: January 19, 2017 By: s/Christina L. Saveriano

Eric I. Abraham Christina L. Saveriano

HILL WALLACK LLP

21 Roszel Road Princeton, New Jersey 08540 Telephone: 609-924-0808

Facsimile: 609-452-1888 eabraham@hillwallack.com csaveriano@hillwallack.com

Attorneys for Defendant Richard P. Junghans, M.D., Ph.D.

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing

DR. RICHARD P. JUNGHANS' ANSWER TO THIRD AMENDED COMPLAINT

is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

January 19, 2017	/s/Christina Saveriano
Date	Christina Saveriano